[00126] The at least one skin-piercing element may also include one or more fluid enhancing elements for stimulating the production or expression of physiological fluid from the site. For example, a vibration element may be operatively associated with the present device or with the at least one skin-piercing element of the device, where such a vibration device is capable of vibrating at a frequency in the range of about 10 to 1000 Hz. In certain embodiments, the fluid enhancing means may include, in addition to or in place of other fluid stimulating elements, a temperature element to increase the temperature of the site to stimulate fluid expression.

V. Test Strips

[00127] The device may be adapted to receive or otherwise be operatively associated or in communication with standard analyte concentration determination test strips, *e.g.*, glucose reagent test strips. In many devices of the subject methods, one or more test strips are capable of being loaded directly into the device, *i.e.*, the present device is configured to receive at least one test strip, before, during or after the physiological sample is extracted. Examples of such a reagent test strips suitable for use with the subject invention include those described in copending U.S. Application Serial Nos. 09/333,793; 09/497,304; 09/497,269; 09/736,788 and 09/746,116, and U.S. Patent Nos. 5,563,042; 5,753,452; 5,789,255, the disclosures of which are herein incorporated by reference.

[00128] In those embodiments where a reagent test strip is in communication with the device, an element for automatically determining the concentration of an analyte in a physiological sample may also be included in the device, where such automatic elements, *e.g.*, automatic meters, are well known in the art. Examples of such automatic elements adaptable for use with the present invention include those described in U.S. Patent Nos. 4,734,360; 4,900,666; 4,935,346; 5,059,394; 5,304,468; 5,306,623; 5,418,142; 5,426,032; 5,515,170; 5,526,120; 5,563,042; 5,620,863; 5,753,429; 5,573,452; 5,780,304; 5,789,255; 5,843,691; 5,846,486; 5,968,836; 5,972,294 and described in copending U.S. Application Serial Nos. 09/333,793; 09/497,304; 09/497,269; 09/736,788 and 09/746,116, the disclosures of which are herein incorporated by reference.

[00129] Referring now to the drawings, Figure 3 provides a representation of an exemplary device of the subject invention showing a cut-away view of the proximal portion of the device. Figure 3 shows device 2 made-up of an outer housing 18, which includes a visual display or liquid crystal display 4 for displaying results to a user of the device (as mentioned above, information may also be audibly communicated to the user in stead or in addition to being visually displayed) and a proximal orifice 10, where the proximal orifice of the device 2 is in communication with, or is in close proximity to, an area of skin S. A cut-away view of the proximal portion 8 of the device 2 reveals the inner components of the subject device. Accordingly, device 2 includes flow characterization element 12, sample type characterization element 14, temperature sensor 16 and microprocessor 6.

[00130] Figure 4 provides a representation of an exemplary proximal portion of the subject device, showing a cut-away view of the proximal portion. In this particular embodiment, the proximal portion 32 of the device 30 is shown, where a proximal portion 32 of device 30 includes a flow characterization element made up of temperature characterization element 22 and a sample type characterization element which includes laser diode 20 and laser diode 21 and detectors 23 and 25. Further included in this embodiment is at least one skin-piercing element 24, operatively associated with spring mechanism 26. Device 30 includes reagent test strip 28, where test strip 28 may be in communication with an internal lumen of the at least one skin-piercing element 24 (not shown) or some other elongated tube or transfer element, through which sample is drawn to the test strip 28. It will be apparent, however, that test strip 28 may be separate from and/or otherwise adjacent to the skin-piercing element 24.

KITS

[00131] Also provided by the subject invention are kits for use in practicing the subject methods. The kits of the subject invention include at least one subject device, where such a device includes at least one flow characterization element for characterizing the flow of a potential physiological sampling site and/or may include a sample type characterization element for determining the type of fluidic contents of the site. Oftentimes the kits of the subject invention include a plurality of such devices. The kits may also include a reusable or disposable lancing element, if not already integrated into

the device. Furthermore, the kit may also include a reusable or disposable meter, if not already integrated into the device, that may be used with reusable or disposable test strips used with the subject invention. Certain kits may include various types of test strips, *e.g.*, where various test strips contain the same or different reagents, *e.g.*, electrochemical and/or colorimetric test strips. Finally, the kits may further include instructions for using the subject devices for determining a suitable physiological fluid sampling site and/or for determining the concentration of at least one analyte in a physiological sample. The instructions may be printed on a substrate, such as paper or plastic, *etc.* As such, the instructions may be present in the kits as a package insert, in the labeling of the container of the kit or components thereof (*i.e.*, associated with the packaging or sub-packaging) *etc.* In other embodiments, the instructions are present as an electronic storage data file present on a suitable computer readable storage medium, *e.g.*, CD-ROM, diskette, *etc.*

EXPERIMENTAL

[00132] The following example correlating skin temperature with fluid volume is offered by way of illustration and not by way of limitation.

[00133] A fine thermocouple (0.002 inch type CHAL from Omega Technologies Corp.), associated at the end of a Penlet® Plus Blood Sampler using a FinePoint™ lancet from LifeScan , Inc., was used to measure the temperature of a sampling site and to access and obtain sample therefrom. As such, the thermocouple was positioned in the center of the orifice of the Blood Sampler having a variable depth setting fixed to 6. A location on the upper forearm of a subject was chosen as a sampling site. The temperature of the site was measured and the site was lanced substantially immediately thereafter. Sample which was readily expressed for a period of about 30 seconds was collected and the weight thereof was determined. This procedure was repeated for a sample size of 21.

[00134] Figure 5 shows the results of the amount of blood volume, represented by sample weight, collected for each temperature. The graph shows that there is a clear correlation between temperature of a site and the weight or volume of sample obtainable therefrom. There is one outlier at about 29.1°C, which may be attributed to a deeper lancing depth or the like.